

International Conference on Harmonization (ICH)
M2 EWG Meeting - Summary
Video Conference Meeting, 22 October - 24 October 2001

Participants:

EU: Stan van Belkum, Miguel Bley, M. T. Carrasco Benitez, Tim Buxton

EFPIA: Andrew Marr, Raj Long

FDA: Greg Brolund (Rapporteur), Melissa Chapman, Bill Ridgely, Norman Schmuff

PhRMA: Kris Arora, Bob Hizer

MHLW: Mihoko Okada, Tetsunari Kihira, Hiroshi Yamamoto

JPMA: Tadao Akiyama, Hitoshi Asano, Harv Martens, Yuichi Nagoshi, Masatoshi Ozeki, Keiji Sawamukai, Tetsuro Shimokariya, Koichi Takahashi

Observer: Bob Kapitany, Tomas Hansson, (Canada), John Hems (IGPA), Andreas Franken (WSMI)

The following are the agreements and discussion item from this meeting:

1. Test eCTD submissions were prepared and evaluated in all three regions. A fairly large number of questions, mostly relatively minor, were raised during this process. Most will be addressed by DTD and specification changes. The remainder will be forwarded to the CTD Implementation Working Group to be included in the CTD Question and Answer documents.
2. A maximum file name length of 64 characters for files and folder names in the eCTD was agreed after discussion. It was agreed that the spreadsheet in the eCTD would not be altered to expand any file names from 32 to something longer if the file name had been abbreviated. Research and testing will be done to ensure that we do not encounter problems with file path lengths once we have gone to this longer name.
3. Agreement was reached on the following guidance regarding the recommended file and folder structure provided in the eCTD specification:

"An example representative structure is presented in this specification. This could be used in most instances, however sponsors may modify this specification where necessary.* For example, to include an additional folder for information where an appropriate folder name is not available in the eCTD specification. It is recommended that sponsors maintain folder names listed in this example. This should not be interpreted to mean that the actual eCTD.DTD XML backbone may be changed or altered in any way.

*Regulatory authorities should be notified of additions and changes to the folder structure according to regional guidance."

4. In some cases in the current CTD and eCTD a single file is recommended for a particular section of the submission. It may be appropriate in some instances to provide multiple files instead of a single file. Therefore, the eCTD specification for files and folder recommendations will be modified to always provide a folder name, even if a single file is to be submitted.
5. The names of folders that are repeatable, such as the drug substance folder, will include the identifying information in the folder name, even if there is only one occurrence of the folder.
6. Agreed to modify the DTD and spreadsheet as needed to clarify required elements, repeatable elements and tag name spelling. Also agreed to limit node extensions to the lowest "leaf" level.

7. The next version of the eCTD specification will normalize the terminology and specific recommendations, such as file name length, throughout the document.
8. The question of the maximum size that should be allowed for any single file in the submission was discussed. Industry representatives will collaborate on a proposal.
9. Appendix 4 (the Excel spreadsheet showing CTD names/Elements names/File names etc) will be updated and formatted so that it can be included as an MSWord table in the eCTD specification.
10. Further investigation will be conducted on the availability in all regions of tools to help automate the process of creating bookmarks and hyperlinks in PDF documents.

The EWG agreed to work toward the goal of signing the Step 2 document prior to the February meeting. These target dates were agreed:

1. November 9, 2001 - Complete action items from this meeting
2. November 23, 2001 – Distribute the updated version of the specification, including the DTD.
3. Week of December 10 – Meet via videoconference for 1 day to agree on the Step 2 specification.

The next ICH Steering Committee meeting is in Brussels the week of February 4-7, 2002